IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		**Docket No.:**	**4240-138**
Applicants:	**KIM, Jung Moon, et al.**	**Conf. No.:**	**9719**
Application No.:	**10/560,329**	**Art Unit:**	**1609**
Date Filed:	**December 10, 2005**	**Examiner:**	**Stacey Nee MacFarlane**
Title:	**NON-ACTIVATED POLYPEPTIDES HAVING A FUNCTION OF TISSUE REGENERATION AND METHOD FOR PREPARING THE SAME**	**Customer No.:**	**23448**

FACSIMILE TRANSMISSION CERTIFICATE
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5
Number of Pages

Steven J. Hultquist

July 21, 2007
Date

RESPONSE TO JUNE 26, 2007 OFFICE ACTION IN U.S. PATENT APPLICATION NO. 10/560,329

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This responds to the June 26, 2007 Office Action in the above-identified application.

Restriction Requirement; Election of Claims

In the June 26, 2007 Office Action, the Examiner has required restriction under the provisions of 35 U.S.C. 121 between:

> **Group I, claim(s) 1-9 and 18-22**, drawn to vectors and compositions comprising a non-activated tissue-regeneration polypeptide (TRP)containing (a) a protein transduction domain (PTD) allowing the polypeptide to permeate the cell without membrane receptors, (b) a furin activation domain (FAD) which has at least one proprotein convertase cleavage site and is cleaved to form an active tissue regeneration domain, and (c) a non-activated protein transduction domain which is activated by convertase cleavage.
>
> **Group II, claim(s) 10 and 11**, drawn to a recombinant vector with an FAD-encoding base sequence, a 5' TRD-encoding DNA, a PTD base sequence, a base sequence for tagging and at least four histidine-encoding base sequences for separation and purification.
>
> **Group III, claim(s) 12-17**, drawn to a method for preparing non-activated TRP comprising (a) culturing transformed bacteria and (b) centrifuging, removing the polypeptide and purifying the polypeptide.

In response, Applicants hereby elect **Group I claims 1-9 and 18-22.** Such election of claims is made without traverse[1], and is made without prejudice to the traversal of the election of species set out hereinafter, for the Group I claims.

[1] It is pointed out, however, that the stated basis for restriction is in error. The Office Action at page 3 thereof states that U.S. Patent 6,672,574 "recites that calcitonin is a treatment of osteoporosis, a bone deteriorating disease...thus teaching a tissue-regeneration polypeptide." Calcitonin is a natural hormone composed of 32 amino acids that is released into the blood stream by the thyroid gland, and binds to osteoclasts to inhibit bone resorption. It is not a tissue regeneration polypeptide.

Restriction of Species; Election With Traverse

In the June 26, 2007 Office Action, the examiner has further required election from among the species identified in Table 1 below, in the left-hand column thereof. In response, applicant elects, **with traverse**, the species identified in the middle column of Table 1 below. The claims readable on such elected species are set out in the right-hand column of Table 1 below.

TABLE 1

Species	Applicants' Elected Species	Claims Readable on Elected Species
one of the TRD polypeptides: BMPs, TGF-β, β-NGF (β-nerve growth factor), β-amyloid, ADAMs (a disintergrin and metalloproteinase-like), TNF-α, MMPs (matrix metalloproteinases), and insulin-like growth factor (IGF-1), (Claim 5 or 13)	**BMPs**	**1-9 and 18-22**
a single corresponding sequence from SEQ ID NOs: 1-13 (Claims 6 or 14)	**SEQ ID NO: 1**	**1-9 and 18-22**
one FAD sequence from SEQ ID NOs: 14 to 26 (Claim 7 or 15)	**SEQ ID NO: 14**	**1-9 and 18-22**
one of the PTD sequences: TAT, drosophila melanogaster-derived Antp peptide, VP22 peptide and mph-1-btm (Claim 8 or 16)	**TAT**	**1-9 and 18-22**
one of the following growth factors: TGF-β, IGF, PDGF, or FGF (Claims 20 and 22)	**TGF-β**	**1-9 and 18-22**

The traversal of the species election requirement is based on the fact that the criterion for species election requirement has not been met. The Office Action states that that "[T]here is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics."

The mere allegation of "search burden" is inconsistent with the standard set forth in MPEP §808.01(a) ("...a requirement for restriction is permissible if... there would be a serious burden

on the examiner if restriction is not required" (emphasis added)). Every effort involves some burden, even if it is *de minimus* in character. This is recognized by the MPEP, by requiring that there be a "serious" burden – substantively more than a mere burden. The Office Action, however, does not allege or support a "serious" burden. It is not clear that "a different field of search" is involved – no search classes/subclasses have been specified for the respective species, no different "electronic resources" have been identified, and no different search queries have been set forth – there is thus no evidence of record that any "burden" occasioned by the search of all species would be of a "serious" character.

The further remarks that "prior art applicable to one species would not likely be applicable to another species" and that "the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph" are mere speculation and as such do not embody probative evidence of any added burden, much less a "serious" burden.

In addition, the assertion that the species are properly restricted for election due to "their mutually exclusive characteristics" has no supportive basis, and it is not in any way apparent what such "mutually exclusive characteristics" comprise, since no specific characteristics have been identified.

The TRD is a secreted protein showing the activity to stimulate the growth or formation of tissue or to induce regeneration of tissue. Each of the 8 species share this character.

SEQ ID NOs: 1-13 are TRD polypeptide sequences. Each of the sequences thus shares this character.

The FAD has a proprotein convertase cleavage site and can be cleaved by the proprotein convertase in cells to activate the TRD. Each of the species shares this character.

SEQ ID NOs: 14-26 are FAD amino acid sequences. Each of the sequences thus shares this character.

The PTD is a protein transduction domain, and each of the species shares this character.

All of TGF-β, IGF, PDGF and FGF are growth factors and each thus has a common character.

It therefore is apparent that there is no *prima facie* basis for requiring species election.

Accordingly, it is respectfully requested that the species set forth in claims 1-22 be retained in consolidated form for examination, and that examination of this application proceed, consistent with this response to the June 26, 2007 Office Action.

Respectfully submitted,

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